

REMARKS

A - Election of an Invention

By the above-mentioned Office Action, the Examiner has required restriction of the above-identified application to one of the following inventions 35 U.S.C. 121.

Group I: Claims 1-29 and 37-40, drawn to a method for determining a predisposition or presence of prostate cancer, classified in class 435, subclass 6.

Group II: Claims 30-36, drawn to a diagnostic kit, classified in class 435, subclass 810.

B - Election of Species

In addition, the Examiner has identified four different families of species for which separate species elections are allegedly required, as follows:

(i) In claim 2, **second specific prostate nucleic acids** comprising PSA, human kallikrein 2, PSMA, transglutaminase 4, acid phosphatase, and PCGEM1 nucleic acid;

(ii) In claim 7, **RNA amplification methods** comprising nucleic acid sequence-based amplification (NASBA), polymerase chain reaction (PCR), transcription mediated amplification assay (TMA), and ligase chain reaction;

(iii) In claims 10 and 12, **detection methods** comprising fluorescence, chemiluminescence, colorimetry, and molecular beacon;

(iv) In claim 22, **samples** comprising urine, blood or a fraction thereof, and prostate biopsy.

It is respectfully submitted that the Restriction Requirement is in error and places an undue burden on Applicants to obtain a reasonable scope of patent protection for the

invention. The U.S. Patent and Trademark Office has recognized this burden and has implemented the following policy with respect to Restriction Requirement practice concerning sequences:

[T]o further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Director has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

It has been determined that normally ten sequences constitutes a reasonable number for examination purposes. Accordingly, in most cases, **up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction.** MPEP § 803.04 (emphasis added).

Therefore, Applicants are entitled to have at least ten sequences searched in the present application.

Further, searching the six nucleotides in claim 2 together does not present a “serious burden” on the examiner. MPEP § 803 (“If the search and examination of an entire application can be made without serious burden, the examiner **must** examine it on the merits, even though it includes claims to independent or distinct inventions.” (emphasis added)). Thus, the PTO **mandates** examination of an entire application if examination can be made without serious burden, even if such an application includes claims to independent or distinct inventions.

Searching the species of the present invention together does not create a “serious burden.” For example, claim 2 of the present invention relates to the detection of PCA3 and a second prostate-specific nucleic acid. Therefore, a search using a PCA3 sequence and generically a second prostate specific nucleic acid should identify potentially relevant art without “serious burden.” Further, the claimed second prostate specific

nucleic acid sequences share similar functionalities (*e.g.*, they are expressed in the prostate) and can thus be used to validate, confirm or improve the determination of prostate cancer presence or predisposition in accordance with the present invention. Because of this functionality, the small number of species and in view of the Patent Office's new policies, Applicants submit there is no "serious burden" to search all of the claimed sequences.

In any event, Applicants also reserve all rights in the non-elected inventions and species, including the right to file one or more divisional applications covering the subject matter thereof.

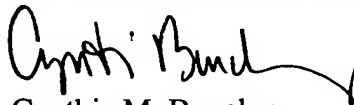
Conclusion

Applicants believe that this is a full and complete response to the Restriction Requirement dated February 3, 2006. Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Cynthia M. Bouchez
Attorney for Applicants
Registration No. 47,438

Date: May 3, 2006

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

528046_1.DOC